

REMARKS

Reconsideration of the application in view of the above amendments and the following remarks is respectfully requested.

Claims 9, 11 and 12 are pending in the subject application. As shown above, claims 9, 11 and 12 have been amended to more clearly set forth the claimed invention pertaining to human prostatic acid phosphatase. Support for the amendments is found, for example, at page 9, lines 8-11, and claim 12 as originally filed, of the subject application. No new subject matter has been added. Therefore, amended claims 9, 11 and 12 are now pending in the subject application.

In the Office Action dated March 9, 2004, all the rejections and objections set forth in the previous Office Action were withdrawn. The Examiner is thanked for considering Applicant's previous response, for withdrawing the rejections and for making the present Office Action non-final.

In the present Office Action, there was a single rejection of claims 9, 11 and 12. The pending claims were rejected under 35 USC § 103(a) as unpatentable over Carson et al. (U.S. Patent No. 5,679,647) in view of Laus et al. (U.S. Patent No. 6,080,409). Applicants respectfully disagree and traverse this grounds of rejection.

Carson et al. discusses Mamula et al. (*J. Immunol.* 152:1453-1461, 1994) at column 29, lines 56-60. Carson et al. states: "It has been reported in the art that T lymphocyte tolerance to self-antigens is more effectively broken through co-immunization of the host with self antigens and foreign antigens that resemble self-antigens (see, Mamula, et al., *J. Immunol.*, supra at 1456)." This characterization of Mamula et al. by Carson et al. is misleading. Mamula et al. is reviewed in detail in Applicants' prior response dated September 26, 2003. As described in Applicant's prior response, Mamula et al. does not disclose that foreign proteins can activate an autoimmune T cell response in the absence of immunization with the self antigen. Based on Mamula et al., breaking T cell tolerance to self antigen requires (rather than, as stated in Carson et al., is "more effectively broken through") co-immunization with foreign antigens and self antigens. Further, Carson et al. provides no evidence that a foreign protein alone can activate an autoimmune T cell response to a tumor self antigen. In particular, a review of Carson et al.,

including the Drawings and Examples, shows that no evidence is disclosed using a tumor self antigen. Therefore, independent of the fact that human prostatic acid phosphatase (PAP) is not disclosed in either Mamula et al. or Carson et al., neither of these references teaches that a foreign protein alone can activate an autoimmune T cell response to a tumor self antigen. Applicants respectfully submit that Carson et al. is missing more than simply that it does not teach PAP as a tumor associated antigen. There is no reasonable expectation for success of Applicants' method based on Carson et al.

In the Office Action, Laus et al. is asserted to provide motivation for one of ordinary skill in the art at the time of Applicants' invention to substitute PAP into the method taught by Carson et al. As described above, Applicants respectfully dispute what Carson et al. is fairly read to have taught. Applicants believe that substituting PAP from Laus et al. into Carson et al. would, at best, be use of PAP in the co-immunization method. Further, Laus et al. describes the use of native PAP combined with the dendritic cell binding protein GM-CSF to stimulate antigen presenting cells (dendritic cells) which are used to prime CTL. (It is noted that that approach has no bearing on Applicants' invention.). Laus et al. is cited in the Office Action as providing motivation to use PAP in a non-coimmunization method based on the statement in Laus et al. that there is "no evidence from the literature that PAP by itself might serve as an inducer and target of CTL." Assuming that this is, in fact, motivation to try Applicants' method (as opposed to motivation to try the method used by Laus et al.), this is at best an invitation to experiment. There is no reasonable expectation for success of Applicants' method based on the teachings of Laus et al.

There is no reasonable expectation for success of Applicants' method based on Laus et al. or Carson et al. or their combination. This is reinforced by Mamula et al. which teaches co-immunization and teaches away from non-coimmunization. (Mamula et al. teaches away because Mamula et al. teaches that immunization with foreign antigen alone elicits T cell responses to foreign antigens but not to self antigen. See for example, Applicants' prior response and Mamula et al. at page 1455, left column, last paragraph.)

Notwithstanding the fact that neither Carson et al. or Mamula et al. teaches Applicants' invention as it pertains to PAP, in order to expedite allowance the pending claims have been amended as set forth above to exclude co-immunization. It is noted that the subject application (at page 10, lines 21-22) recites: "Additionally, a foreign protein or peptide or both may be used in combination with a human self tumor antigen." By the use of the term "Additionally", it was clear that the inclusion of a human self tumor antigen was optional. The amended pending claims as they relate to PAP exclude that option. Therefore, the amended pending claims do exclude the co-administration of unmodified PAP.


Accordingly, it is submitted that the rejection of claims 9, 11 and 12 under 35 USC § 103(a) over Carson et al. and Laus et al. has been overcome and withdrawal of the rejection is respectfully requested.

Therefore, in light of the amendments and remarks set forth above, Applicants believe that the Examiner's rejection has been overcome. Reconsideration of the application and allowance of the pending claims (9, 11 and 12) are respectfully requested. If there is any further matter requiring attention prior to allowance of the subject application, the Examiner is respectfully requested to contact the undersigned attorney (at 206-622-4900) to resolve the matter.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,

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